

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

**K-V PHARMACEUTICAL COMPANY,)
THER-RX CORPORATION,)
v.)
Plaintiffs,) Case No. 3:12-cv-02088-JFA
)
ANTHONY KECK,)
Defendant.)**

CONSENT ORDER

This Order is entered on the consent of the parties, who, by their signatures below, have stipulated that:

1. K-V Pharmaceutical Company is a corporation organized under the laws of Delaware and headquartered in St. Louis, Missouri.
2. Ther-Rx is a corporation organized under the laws of Missouri and headquartered in St. Louis, Missouri. K-V and Ther-Rx are referred to herein collectively as "KV."
3. Anthony Keck is the Director of South Carolina Department of Health and Human Services ("SCDHHS"). KV and SCDHHS are hereinafter referred to as the "Parties."
4. Makena[®] is a drug approved by the U.S. Food and Drug Administration ("FDA") that is used to lower the risk of preterm birth in women who are pregnant with a single baby and have had a prior preterm birth of a single baby. Makena[®] is made with the active pharmaceutical ingredient ("API") hydroxyprogesterone caproate ("17P").

5. Ther-Rx has executed a Medicaid Drug Rebate Agreement ("MDRA") with the United States Department of Health and Human Services and a State Supplemental Rebate with the South Carolina Department of Health and Human Services.

6. SCDHHS is the single state agency responsible for the administration of the South Carolina State Plan and Medicaid program in South Carolina, and makes all final decisions and determinations regarding the administration of the Medicaid program.

7. SCDHHS is allowed to delegate some of its duties by entering into contracts with Managed Care Organizations ("MCOs"), but only if SCDHHS retains final decision making authority and ensures the MCOs' compliance with the State plan, as well as federal and state laws and regulations. Any such contracts must be approved by the Centers for Medicare and Medicaid Services ("CMS") and SCDHHS is required to "ensure that all services covered under the State plan are available and accessible to enrollees of MCOs." 42 C.F.R. § 438.206(a).

8. Likewise, federal regulations require the MCOs to furnish services "in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid." 42 C.F.R. § 438.210(a)(2).

9. The MCOs are the agents of SCDHHS and manage the provision of Medicaid on behalf of SCDHHS to eligible beneficiaries in South Carolina. As such, the MCOs do not have the authority to change or disapprove of any administrative decision of SCDHHS, or otherwise substitute their judgment for that of SCDHHS regarding the applications of SCDHHS policies. *K.C. et al. v. Shipman et al.*, 716 F.3d 107 (4th Cir. 2013).

10. The following MCOs have entered into contracts with SCDHHS to provide services to Medicaid beneficiaries in South Carolina: Wellcare Health Plan, Inc., BlueChoice HealthPlan, First Choice by Select Health, Absolute Total Care, Molina Healthcare, Inc. and

Advicare. SCDHHS may execute contracts with additional MCOs in the future (collectively, the "MCO Contracts").

11. In the MCO Contracts, the MCOs agreed to comply with all state and federal laws, regulations and policies that may be applicable. The MCOs also agreed to comply with the applicable policies and procedures of SCDHHS and not to impose limitations or exclusions with respect to covered benefits and related services that are more stringent than those specified in SCDHHS's policies. SCDHHS agreed to monitor the MCOs' compliance with the contract, the MCO Policy & Procedure Guide, and applicable federal and state laws and regulations.

12. Further, the MCO Contracts require SCDHHS to provide administrative oversight of the MCOs and clarification of the changes in the MCO program and Medicaid policies, regulations and procedures.

13. On July 25, 2012, KV filed a lawsuit (the "Lawsuit") against Anthony Keck, in his official capacity as Director of SCDHHS, alleging that SCDHHS violated the Medicaid Act, 42 U.S.C. 1396r-8 and 1396a(a)(10) by failing to cover Makena®. SCDHHS denied the allegations in the Lawsuit.

14. On December 20, 2013, the Parties executed a Settlement Agreement And Release (with selected confidential terms) (the "Settlement Agreement") resolving the issues in the Lawsuit.

15. Pursuant to the Settlement Agreement, SCDHHS agreed among other things, to change its policy regarding Makena®. Specifically, SCDHHS agreed:

(a) to approve reimbursement for all prescriptions of Makena® where the patient meets the labeled indications for Makena® at the time of the physician's administration of Makena®;

- (b) to implement a process for specialty pharmacy distribution of Makena®;
- (c) to remove the prior authorization policy it had for Makena®;
- (d) to implement a policy allowing providers to submit prescriptions for Makena® prior to 16 weeks, 0 days gestation but reserves the right to withhold shipment of vials of Makena® by the pharmacy until the 15th week;
- (e) to not disadvantage Makena® for its approved indication in any way nor institute a "step edit" through another drug or therapy, including compounded 17P;
- (f) to ensure that the Makena® copay will not exceed the copay applied to compounded 17P.

16. SCDHHS also agreed to take reasonable steps to ensure that each MCO with whom it currently or subsequently contracts complies with the new Makena® policy and the drug coverage requirements of the Medicaid Act.

17. Although SCDHHS does not require a prior authorization form to be completed for Makena®, it was agreed that the MCOs would be allowed to use a revised form for both Makena® and compounded 17P, with the physician indicating the requested product next to their signature. All other reimbursement requirements for Makena® set forth in paragraph 15 above apply to SCDHHS and its MCOs. The MCOs must comply with SCDHHS's policies and procedures including approval of all prior authorization requests for reimbursement for prescriptions of Makena® where the patient meets the labeled indications for Makena® and the MCO's shall not impose limitations or exclusions regarding Makena® that are more stringent than SCDHHS's policies.

18. SCDHHS distributed a memorandum to the MCOs that instructed the MCOs to provide reimbursement for Makena® through a "buy and bill" system and specialty pharmacies,

to update their policies on Makena®, and to otherwise comply with SCDHHS's new policy regarding Makena®.

In light of the Parties' agreement that SCDHHS institute a new policy for Makena® as part of the settlement of this dispute, and the Parties' agreement that portions of the settlement be entered into a Consent Order, and in light of the foregoing stipulations,

It is **HEREBY ORDERED, ADJUDGED and DECREED** that:

1. SCDHHS must:

- (a) Remove its current prior authorization requirement for prescriptions of Makena and no longer require a prior authorization for Makena®;
- (b) Approve reimbursement for all prescriptions of Makena® where the patient meets the labeled indications for Makena® at the time of the physician's administration of Makena®;
- (c) Implement a process for specialty pharmacy distribution of Makena®;
- (d) Implement a policy allowing providers to submit prescriptions for Makena® prior to 16 weeks, 0 days gestation but reserves the right to withhold shipment of vials of Makena® by the pharmacy until the 15th week;
- (e) Not disadvantage Makena® for its approved indication in any way, nor institute or permit a "step edit" through another drug or therapy, including but not limited to compounded 17P;
- (f) Ensure that the Makena® copay will not exceed the copay applied to compounded 17P.

2. The MCOs who enter into MCO Contracts with SCDHHS are agents of SCDHHS and are in active participation with SCDHHS for the purposes of carrying out SCDHHS's responsibilities under the Medicaid Act and must make all services covered under the State plan

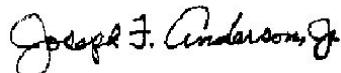
available and accessible to its enrollees. The MCOs must comply with SCDHHS's policies and procedures including approval of all prior authorization requests for reimbursement for prescriptions of Makena® where the patient meets the labeled indications for Makena® and the MCO's shall not impose limitations or exclusions regarding Makena® that are more stringent than SCDHHS's policies.

3. SCDHHS must ensure that, consistent with SCDHHS's fee-for-service Medicaid reimbursement requirements, each MCO:

- (a) reimburses for Makena® if the patient is on label (meets the clinical indication) and the physician requests Makena® as set forth on the attachment to the Medicaid Bulletin issued on December 20, 2013;
- (b) reimburses the physician directly if reimbursement is sought through the buy and bill process;
- (c) reimburses a specialty pharmacy for Makena® if reimbursement is sought through the pharmacy benefit;
- (d) updates all relevant provider manuals, websites, newsletters or other publications with these policies for reimbursement of Makena® and issues a communication announcing these policies that, to the greatest extent reasonably possible, will reach the relevant provider community.

4. This case is DISMISSED WITH PREJUDICE, each party to bear its own costs.

IT IS SO ORDERED.



Joseph F. Anderson, Jr.
United States District Judge

April 16, 2014
Columbia, South Carolina

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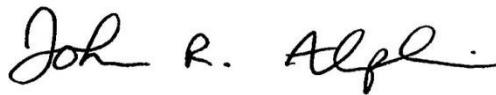
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